510(k) SUMMARY

FEB 2 8 2013

Facet-Link, Inc. Facet Screw System

Applicant Information:

Facet-Link, Inc.
200 Roundhill Drive
Rockaway, NJ 07866

Phone: 973-627-4171
Facsimile: 973-718-4672
Contact Person: Massimo Calafiore
Date Prepared: November 9, 2012

Device Information:

Trade Name:	Facet Screw System
Common or Usual Name:	Facet Screw Spinal Device System
Classification:	Unclassified
Product Code:	MRW
Predicate Device:	NuVasive Facet Screw System (K101284) Depuy Discovery Facet Screw Fixation System (K012773)

Intended Use / Indications for Use:

The Facet-Link Facet Screw System is intended to stabilize the spine as an aid to fusion through immobilization of the facet joints. The methods of fixation are:

> Transfacet fixation - The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle.
>
> Translaminar-facet fixation - The screws are inserted bilaterally through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet across the facet joint and into the inferior pedicle.

The Facet-Link Facet Screw System is indicated for facet fixation, with or without bone graft, at single or multiple levels, from C2 to S1 (inclusive). The Facet-Link Facet Screw System is indicated for treatment of any or all of the following:

(a) pseudoarthrosis and failed previous fusion;

(b) spondylolisthesis; and

(c) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies.

The Facet-Link Facet Screw System is intended for conventional surgical placement.

Technological Characteristics:

The Facet-Link Facet Screw System consists of a conical and threaded head, partially threaded lag screws and fully threaded screws designed to compact or fixate juxtaposed facet articular processes to enhance spinal fusion and stability. The screws and washers are fabricated from anodized titanium alloy (Ti-6AI-4V) and are supplied in various sizes.

The Facet-Link Facet Screw System requires accessory general instruments for implantation. Instruments required for implantation may include a variety of k-wires, cannulae, drills, taps, and drivers.

Safety and Performance Data:

The following in vitro bench tests have been performed for the Facet-Link Facet Screw System, in accordance with ASTM F1717, ASTM F2193, and ASTM F543:

- Static Axial Compression via Cantilever Bending Test
- Static Axial Pullout Test
- Dynamic Axial Compression via Cantilever Bending Test

These tests demonstrated that the Facet Screw System meets its intended performance specifications and is substantially equivalent to the predicate devices.

The biocompatibility of the Facet Screw System is based on FDA's clearance of a previously cleared device of the same materials and finish. Cytotoxicity testing following ISO 10993-5 further confirms the biocompatibility of the implant materials. The Facet Screw System has also been evaluated in a magnetic resonance environment and non-clinical testing demonstrated that the Facet Screw System is MR Conditional, in accordance with ASTM F2052-06.

Substantial Equivalence:

The Facet Screw System and the predicate devices have the same intended use and very similar indications for use, technological characteristics and principles of operation. The minor technological differences between the Facet Screw System and its predicate devices do not raise any new types of safety or effectiveness questions. In vitro verification testing demonstrates that the Facet Screw System performs as intended and minor differences from predicates do not impact safety or effectiveness. Thus, the Facet Screw System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

Facet-Link, Incorporated
% Hogan Lovells US LLP
Ms. Janice Hogan
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K123497
Trade/Device Name: Facet Screw System
Regulation Class: Unclassified
Product Code: MRW
Dated: January 30, 2013
Received: January 30, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123497

Device Name: Facet Screw System

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123497